

Technical Data Sheet

Buffered NaCl-Peptone Solution

Ordering number: 1.46369.0010

Buffered NaCl-Peptone Solution is designed for the microbial examination of non-sterile pharmaceutical products according to the European Pharmacopoeia.

The solution is used for the microbial examination of non-sterile pharmaceutical products, e.g. as solution for sample preparation or as dilution or washing solution.

The formulation is prepared according to the recommendations of the current European Pharmacopoeia (EP, 2.6.13.).

The buffered solution is available in different filling volumes and with various locking mechanisms:

- Buffered NaCl-Peptone Solution (article number 146196): 17 ml-**tube**, red, filling volume 9 ml
- Buffered NaCl-Peptone Solution (article number 146141): 17 ml-**tube**, blue, filling volume 9.9 ml
- Buffered NaCl-Peptone Solution (article number 146480): 125 ml-bottle with **screw cap**, filling volume 90 ml
- Buffered NaCl-Peptone Solution (article number 146407): 275 ml-bottle with **wide mouth**, filling volume 90 ml
- Buffered NaCl-Peptone Solution (article number 146367): 125 ml-bottle with **screw cap**, filling volume 100 ml
- Buffered NaCl-Peptone Solution (article number 146369): 125 ml-bottle with **flip cap**, filling volume 100 ml
- Buffered NaCl-Peptone Solution (article number 146360): 250 ml-bottle with **screw cap**, filling volume 90 ml
- Buffered NaCl-Peptone Solution (article number 146419): 250 ml-bottle with **screw cap**, filling volume 200 ml
- Buffered NaCl-Peptone Solution (article number 146611): 250 ml-bottle with **flip cap**, filling volume 200 ml
- Buffered NaCl-Peptone Solution (article number 146408): 500 ml-bottle with **flip cap**, filling volume 300 ml
- Buffered NaCl-Peptone Solution (article number 146585): 1000 ml-bottle with **screw cap**, filling volume 600 ml
- Buffered NaCl-Peptone Solution (article number 146368): 1000 ml-bottle with **screw cap**, filling volume 1000 ml

Mode of Action

The low content of peptone as well as the content of phosphate buffer and sodium chloride in the solution maintains the viability of present microorganisms without supporting growth.

Typical Composition

| | |
|---|---------|
| Peptone | 1 g/l |
| NaCl | 4.3 g/l |
| KH ₂ PO ₄ | 3.6 g/l |
| Na ₂ HPO ₄ · 2 H ₂ O | 7.2 g/l |

The appearance of the medium is clear and colorless. The pH value is in the range of 6.8-7.2. The medium can be adjusted and/or supplemented according to the performance criteria required.

Application and Interpretation

For quality control a stability test is performed in order to test the ability of the solution to maintain viability of microorganisms. Therefore the buffer solution to be tested is inoculated with 100-1,000 CFU/ml. Directly after inoculation as well as after an incubation time of 1 hour at 20 to 25 °C for each test strain 100 µl are subcultured on Columbia Blood Agar (article number 146559). The viable count should not change from the beginning to the end of incubation. A typical stability test is shown under "Quality Control".

Storage and Shelf Life

The product can be used for tests until the expiry date if protected from light and properly sealed at +2 °C to +25 °C.

The testing procedures as described on the CoA can be started up to the expiry date printed on the label.

Disposal

Please mind the respective regulations for the disposal of used culture medium (e.g. autoclave for 20 min at 121 °C, disinfect, incinerate etc.).

Quality Control

| Control Strains | ATCC # | Inoculum CFU | Incubation | Expected Results |
|-------------------------------|--------|--------------|-------------------------|--------------------------------|
| <i>Staphylococcus aureus</i> | 6538 | 2,000-20,000 | 1 h ± 5 min at 20-25 °C | No change in the number of CFU |
| <i>Pseudomonas aeruginosa</i> | 9027 | 2,000-20,000 | 1 h ± 5 min at 20-25 °C | No change in the number of CFU |
| <i>Escherichia coli</i> | 8739 | 2,000-20,000 | 1 h ± 5 min at 20-25 °C | No change in the number of CFU |
| <i>Bacillus subtilis</i> | 6633 | 2,000-20,000 | 1 h ± 5 min at 20-25 °C | No change in the number of CFU |
| <i>Candida albicans</i> | 10231 | 2,000-20,000 | 1 h ± 5 min at 20-25 °C | No change in the number of CFU |

Please refer to the actual batch related Certificate of Analysis.



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Literature

European Pharmacopoeia 8.0 (2014): 2.6.13. Microbial examination of non-sterile products (test for specified microorganisms).

Ordering Information

| Product | Cat. No. | Pack size |
|--------------------------------|--------------|--------------------|
| Buffered NaCl-Peptone Solution | 1.46196.0020 | 20 x 9 ml tube |
| Buffered NaCl-Peptone Solution | 1.46196.0100 | 100 x 9 ml tube |
| Buffered NaCl-Peptone Solution | 1.46141.0020 | 20 x 9.9 ml tube |
| Buffered NaCl-Peptone Solution | 1.46480.0010 | 10 x 90 ml bottle |
| Buffered NaCl-Peptone Solution | 1.46407.0006 | 6 x 90 ml bottle |
| Buffered NaCl-Peptone Solution | 1.46367.0010 | 10 x 100 ml bottle |
| Buffered NaCl-Peptone Solution | 1.46369.0010 | 10 x 100 ml bottle |
| Buffered NaCl-Peptone Solution | 1.46360.0006 | 6 x 90 ml bottle |
| Buffered NaCl-Peptone Solution | 1.46419.0006 | 6 x 200 ml bottle |
| Buffered NaCl-Peptone Solution | 1.46611.0006 | 6 x 200 ml bottle |
| Buffered NaCl-Peptone Solution | 1.46408.0006 | 6 x 300 ml bottle |
| Buffered NaCl-Peptone Solution | 1.46585.0006 | 6 x 600 ml bottle |
| Buffered NaCl-Peptone Solution | 1.46368.0006 | 6 x 1000 ml bottle |
| Columbia Blood Agar Pharm. | 1.46559.0020 | 20 x 90 mm plates |
| Columbia Blood Agar Pharm. | 1.46559.0100 | 100 x 90 mm plates |

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